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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,625

03/01/2006

Gregoire Prevost

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8272

47888 7590 04/28/2008  
HEDMAN & COSTIGAN P.C.  
1185 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER

TUCKER, ZACHARY C

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

04/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/562,625	PREVOST ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>19Jan06</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

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***Lack of Unity of Invention  
~and~  
Requirement for Election of Species***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1 (in part), 2, 3, (2 and 3 not in part), 6-20 and 24-27 (6-20 and 24-27 in part), drawn to a composition comprising an amount of at least one Ccd25 phosphatase inhibitor in combination with at least one other anti-cancer agent, sufficient for the treatment of cancer, wherein the Ccd25 phosphatase inhibitor is a compound of formula (I), and a method of treating cancer in a warm-blooded animal comprising administering such a composition.

Group II, claims 1 (in part), 4 (not in part), 6-20 and 24-27 (6-20 and 24-27 in part), drawn to a composition comprising an amount of at least one Ccd25 phosphatase inhibitor in combination with at least one other anti-cancer agent, sufficient for the treatment of cancer, wherein the Ccd25 phosphatase inhibitor is a compound of formula (II), and a method of treating cancer in a warm-blooded animal comprising administering such a composition.

Group III, claims 1 (in part), 5 (not in part), 6-20 and 24-27 (6-20 and 24-27 in part), drawn to a composition comprising an amount of at least one Ccd25 phosphatase inhibitor in combination with at least one other anti-cancer agent, sufficient for the treatment of cancer, wherein the Ccd25 phosphatase inhibitor is menadione and its analogues, and a method of treating cancer in a warm-blooded animal comprising administering such a composition.

Group IV, claims 1, 6-20 and 24-27, drawn to a composition comprising an amount of at least one Ccd25 phosphatase inhibitor in combination with at least one other anti-cancer agent, sufficient for the treatment of cancer, wherein the Ccd25 phosphatase inhibitor is other than one as set forth in Groups I, II or III above, and a method of treating cancer in a warm-blooded animal comprising administering such a composition.

Group V, claims 21-23, drawn to a compound of (1R)-1-[(2R)-2-amino-3-[(8S)-8-(cyclohexylmethyl)-2-phenyl-5,6-dihydroimidazo[1,2-a]pyrazine-7(8H)-yl]-3-oxopropyl]dithio)methyl]-2-[(8S)-8-cyclohexylmethyl)-2-phenyl-5,6-dihydroimidazo[1,2-

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a]pyrazine-7-(8H)-yl]-2-oxoethylamine, or a pharmaceutically acceptable salt thereof, and a method of making the salt.

The inventions listed as Groups I to V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The Ccd25 phosphatase inhibitors specified in claims 1, 4, and 5 are structurally diverse, and therefore do not share the same or corresponding technical features, and the compound as set forth in Group V does not share the same or corresponding technical features with any other compound set forth in the compositions and methods. The subject matters of the established Groups are non-overlapping, although a common utility is specified.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is also required, therefore, in reply to this action, to elect a single disclosed species of (for Groups I, II or III) an “at least one other anti-cancer agent,” and applicants is required (for Group IV), in reply to this action, to elect a single disclosed species of the Ccd25 phosphatase inhibitor, in addition to a single disclosed species of an “at least one other anti-cancer agent,” to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are

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added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Structurally diverse "at least one other anti-cancer agent(s)" are specified in the claims, and because of the fact that a diverse array of molecular structures are encompassed by the general recitation "at least one Ccd25 phosphatase inhibitor," (with respect to Group IV), not all of which bear the same or corresponding special technical features (structure), the Groups as set forth provide for the basis for establishing Lack of Unity of Invention in the instant case.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

### ***Conclusion***

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 9:00am to 5:00pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

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**Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.**

**/Zachary C. Tucker/  
Primary Examiner  
Art Unit 1624**